

**Johnson County Education Research Triangle
KUMC Clinical Research Center Budget Report**

	Approved FY21 Budget			Actual FY21 as of 06/30/2021		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 6,300,000		\$ 6,300,000	6,569,289		\$ 6,569,289
Clinical Trial Collection		6,500,000	6,500,000		5,903,995	5,903,995
Cancer Research Center Clinical Services		2,750,000	2,750,000		1,577,066	1,577,066
Cancer Center Support Grants for NCI-designated Cancer Centers		400,000	400,000		873,560	873,560
University of Kansas Hospital Community Support		1,182,100	1,182,100		1,064,329	1,064,329
KU Cancer Center Support		1,500,000	1,500,000		344,036	344,036
Facility Rent Collection		383,124	383,124		383,124	383,124
Common Area Maintenance Fee		336,822	336,822		336,822	336,822
Interest Earnings			-	5,403		5,403
Build America Bond Interest Subsidy	147,329	-	147,329	115,518	-	115,518
Total Revenue	6,447,329	13,052,046	19,499,375	6,690,210	10,482,932	17,173,142
Expenditures						
Payroll						
Director, Phase I Program & startup	72,151	198,465	270,616	71,279	163,340	234,619
Physician Positions	147,894	59,450	207,344	147,725	64,806	212,531
Research Leadership	166,782	380,375	547,157	152,195	471,520	623,715
Business Development	-	389,847	389,847	-	284,956	284,956
Research Scientists	116,184	45,500	161,684	30,302	5,419	35,721
Investigator Initiated Trial Staff	353,017	228,023	581,040	321,702	199,224	520,926
Research Laboratory Staff	208,464	372,832	581,296	303,910	410,071	713,981
Research Nursing, Study Coordination & Regulatory	2,900,083	6,385,447	9,285,530	2,473,148	5,704,421	8,177,569
Administration	61,250	1,240,807	1,302,057	1,563	1,213,592	1,215,155
Budget & Finance Support	272,398	727,080	999,478	250,844	648,407	899,251
Total Payroll	4,298,223	10,027,826	14,326,049	3,752,668	9,165,756	12,918,424
Other Operating Expense						
Operating Expenses	125,000	875,000	1,000,000	94,231	951,346	1,045,577
Telephone & Networking	61,139	-	61,139	44,466	-	44,466
Mass Spec Lease	81,048		81,048	87,174	-	87,174
Clinical Trial Research Initiatives for Comprehensive Status	-	250,000	250,000	38,667	260,845	299,512
KUH Clinical Services Settlement Cost - Operations	-	2,750,000	2,750,000	-	2,702,214	2,702,214
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	383,124	383,124
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		336,822	336,822
Total Other Operating Expense	267,187	4,594,946	4,862,133	264,538	4,634,351	4,898,889
Facility Expense						
Facility Operations	856,900	-	856,900	855,841	-	855,841
Withheld by Trustee for Debt Service & Trustee Expenses	1,190,940	-	1,190,940	946,105	-	946,105
Total Facility Expense	2,047,840	-	2,047,840	1,801,946	-	1,801,946
Total Expenditures	\$ 6,613,250	\$ 14,622,772	\$ 21,236,022	\$ 5,819,152	\$ 13,800,107	\$ 19,619,259
Revenue less Expenditures	(165,921)	(1,570,726)	(1,736,647)	871,058	(3,317,175)	(2,446,117)
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	400,000	-	400,000
Less Current Amount Set aside for Operations	200,000	(2,000,000)	(1,800,000)	200,000	(1,500,000)	(1,300,000)
Operating Account - Beginning Balance	2,692,578	526,685	3,219,263	2,572,572	2,049,103	4,621,675
Operating Account - Ending Balance	\$ 1,926,657	\$ 955,959	\$ 2,882,616	\$ 2,843,630	\$ 231,928	\$ 3,075,558

The University of Kansas Medical Center JCERT University Report



THE UNIVERSITY OF KANSAS

CANCER CENTER



October 2021

KU Clinical Research Center Overview

Designed unlike any other clinical research facility in the country, the 82,400-square-foot **KU Clinical Research Center** (KU CRC) is equipped with state-of-the-art features and efficient use of space, resources and manpower to best accommodate patients and researchers. The building was donated by the Hall Family Foundation, totally renovated by the JCERT Authority, and features:

- Cutting-edge cancer trials, easily accessible outpatient rooms, office space and specimen collection labs
- Clinical research functions combined into one location
- Pharmacy to dispense and monitor medications along with pharmacy patient advocates to help with insurance billing questions and issues
- Clinical lab for performing complete blood counts, blood chemistry analysis, urinalysis and preparation of bone marrow biopsies
- A pavilion for gatherings and community events

At the KU CRC, clinical trials are designed to identify safer and more effective approaches to prevention, screening, diagnosis and treatment of cancer. Cancer clinical trials provide access to potential advancements in care and lead to medical innovations in cancer prevention and treatment. These trials may be a patient's best chance for increased survival.

Through the **Early Phase I Oncology Unit**, the KU CRC strives to:

- Introduce new cancer drugs to the market that are more effective and less toxic
- Offer more treatment options to patients
- Develop strong partnerships with referring physicians
- Gain national program recognition

The **Clinical Trials Office (CTO)** provides comprehensive, centralized support services that span the lifecycle of cancer clinical trials from concept through manuscript and assures that the patient population and resources needed to successfully conduct these trials is in compliance with all federal, state and local regulations. The CTO has facilitated significant growth of investigator-initiated clinical research at the KU Cancer Center while implementing and administering cost-effective processes to ensure the research activities have scientific merit, protect patient safety, maintain scientific integrity and are fiscally sound.

Masonic Cancer Alliance (MCA) is the outreach network of The University of Kansas Cancer Center. MCA is a membership-based organization that brings together cancer research, care and support professionals to advance the quality and reach of cancer prevention, early detection, treatment and survivorship. It links member hospitals, medical professionals and their patients with KU Cancer Center research and clinical trials. The administrative offices for MCA are housed in the KU CRC.

The KU CRC is an important component of KU Cancer Center's efforts to achieve Comprehensive Cancer Center designation from the National Cancer Center Institute, which would further position KU Cancer Center and its partners at the forefront of cancer research, treatment and possible cures.



What Our Clinical Trial Patients Say

*"Because of the clinical trial,
I have a life with my children."*

- Corina Ramirez, Clinical Trial Patient

Transforming Cancer Care in Our Region

At The University of Kansas Cancer Center, we are on an urgent journey to break the devastating grip of cancer. Our first step on this journey was to achieve National Cancer Institute (NCI) Cancer Center designation in 2012. We are the only cancer center in the region, and one of only 71 in the nation, to receive this distinction, a symbol of research and clinical excellence. KU Cancer Center's NCI designation allows patients to stay close to home while still receiving the most advanced cancer care from a deep bench of specialists. NCI-designated Cancer Centers are trailblazers in cancer research, recognized for their scientific leadership, resources and depth of their research in basic, clinical and population science.

NCI designation is transforming our region

- Patients treated at NCI centers have a 25 percent greater chance of survival
- More Kansas City patients receive life-saving cancer treatments close to home

Bringing the latest in research and cancer care to Kansans

KU Cancer Center aims to do nothing less than fundamentally transform the cancer experience – to give all people in our region greater access to breakthrough ideas and novel treatments.

Benefiting our community through focused treatment and prevention efforts

- Improve access to prevention services and cancer treatment for underserved and minority communities
- Decrease smoking and obesity rates and increase HPV vaccinations
- Extend the highest level of prevention, treatment and survivorship available

Accelerating progress: Because cancer does not wait

- Develop highly personalized cancer treatments for each unique patient
- Offer state-of-the-art cancer treatments close to home
- Recruit and retain the best physician scientists
- Leverage partnerships for further innovation in drug discovery and development

The next step in our quest to conquer all cancers

Members of The University of Kansas Cancer Center team recently submitted their NCI Cancer Center Support Grant (CCSG) application. The center is submitting for NCI renewal and requesting Comprehensive status.

Comprehensive cancer center designation is the premier ranking awarded by the NCI. Comprehensive cancer centers attain this elite distinction by demonstrating significant depth and breadth in basic, clinical and translational research, with a clear focus on the cancers most affecting their communities. This requires a deep understanding of the cancer issues faced by those we serve and responding with tailored solutions. Comprehensive status would help the cancer center obtain additional research grants, recruit additional researchers and attract more patients.

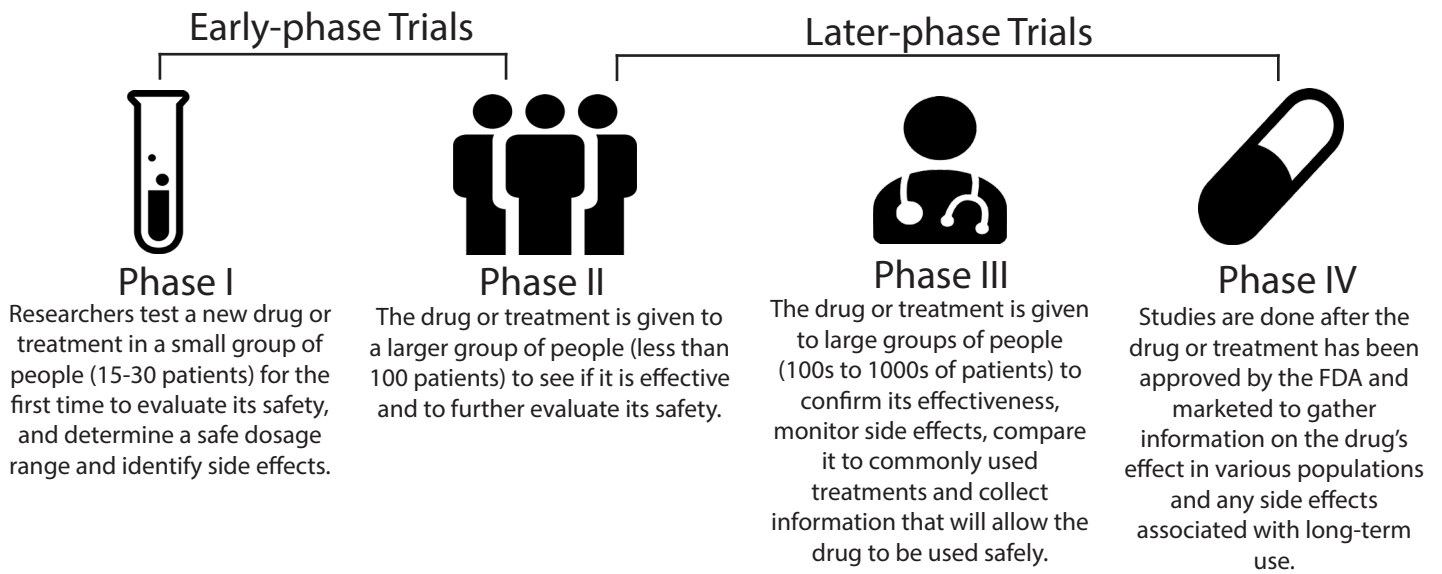
On February 15, 2022, the cancer center will host a virtual site visit for NCI site reviewers, and a decision on the current application is expected by next summer.



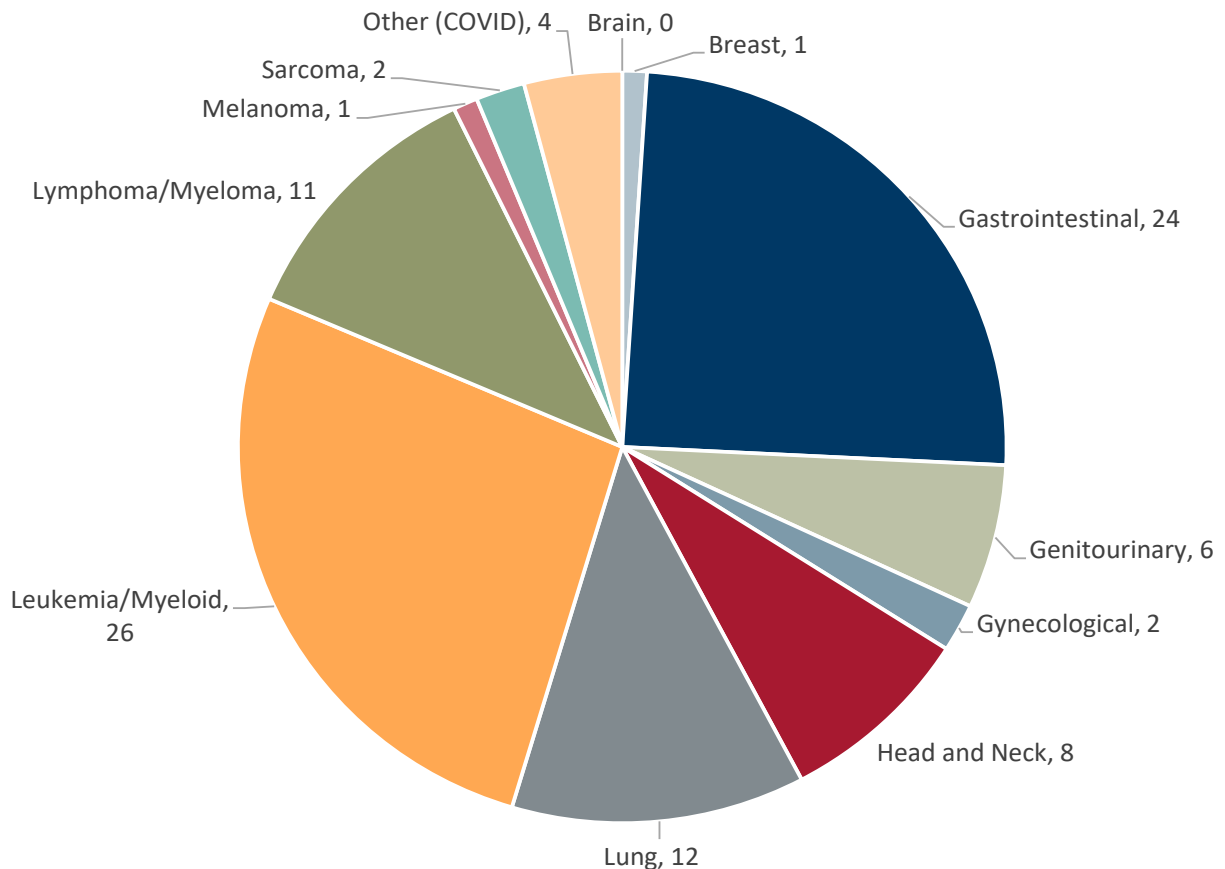
A Cancer Center Designated by the
National Cancer Institute

Types of Clinical Trials

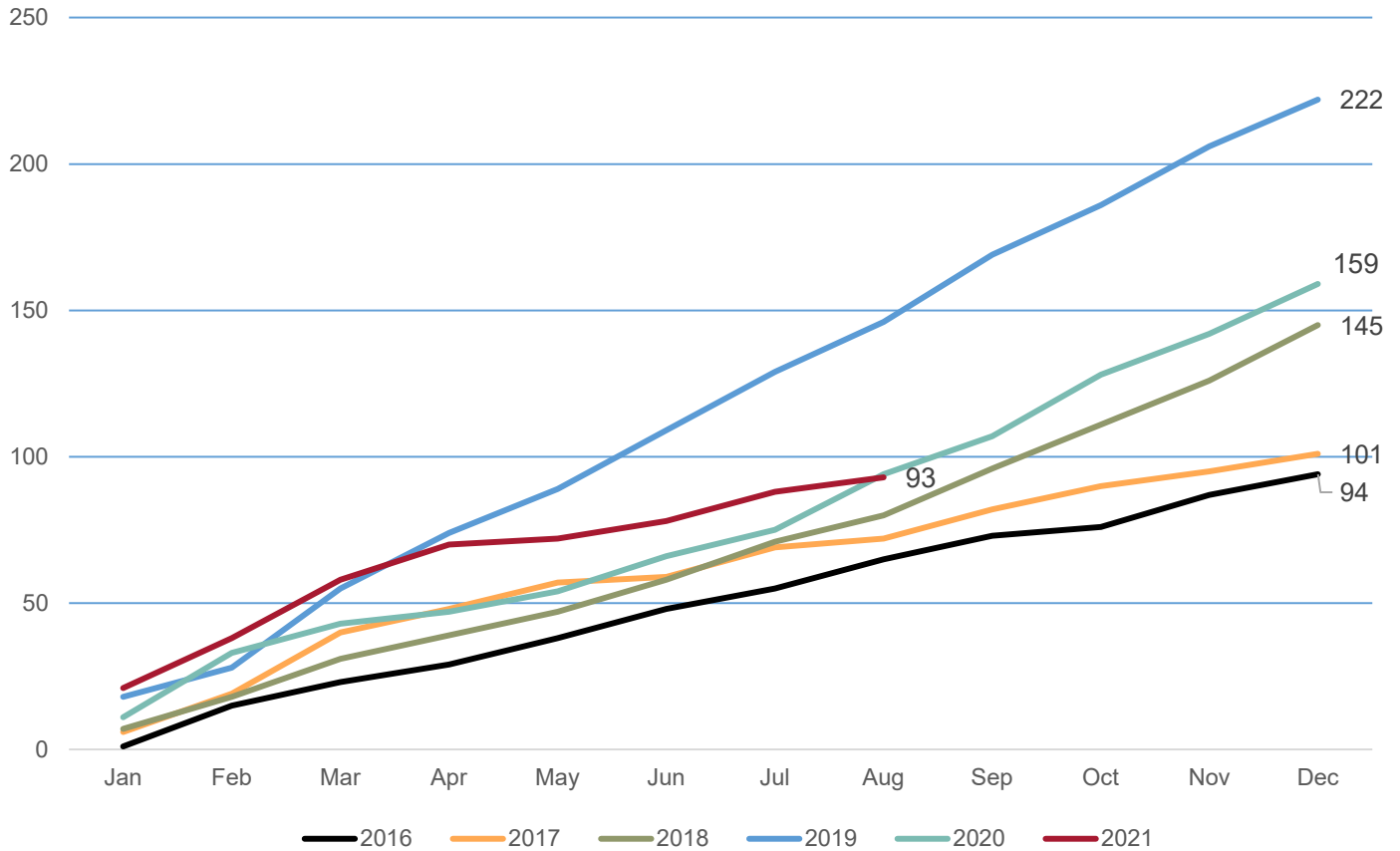
Cancer clinical trials provide access to potential advancement in care and lead to innovations in cancer prevention. Clinical trials are conducted in four phases:



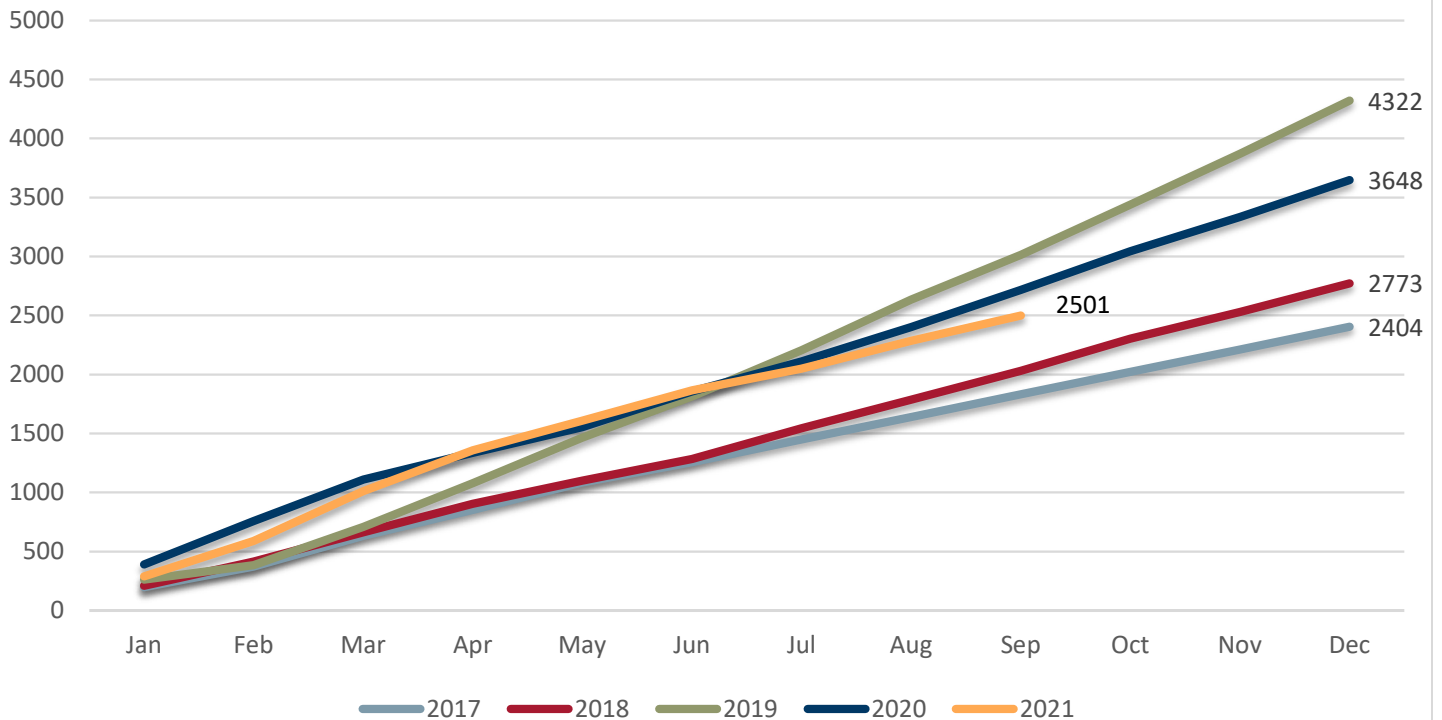
Early-phase Clinical Trial Accrual by Disease Group



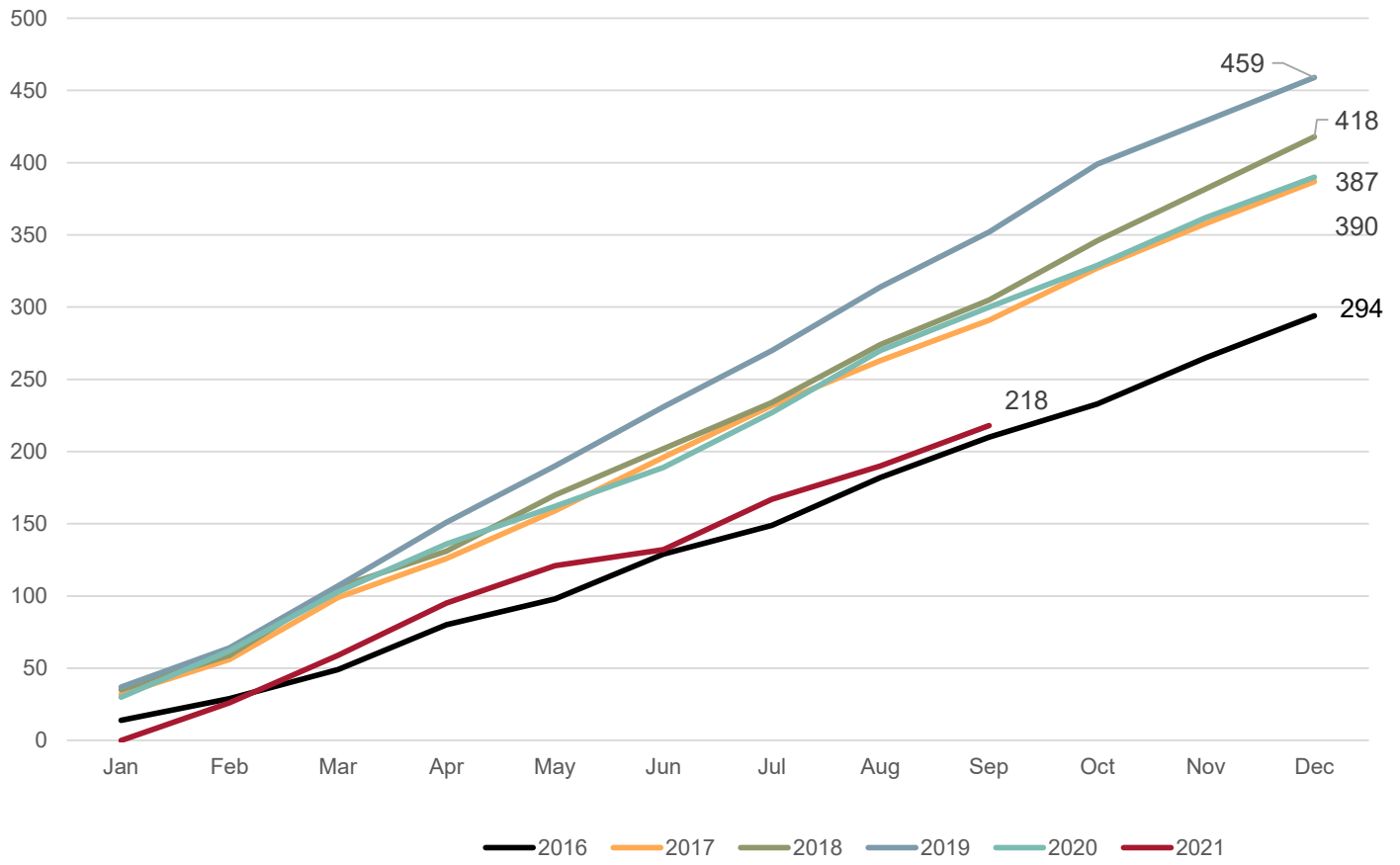
Early-phase Clinical Trial Accrual



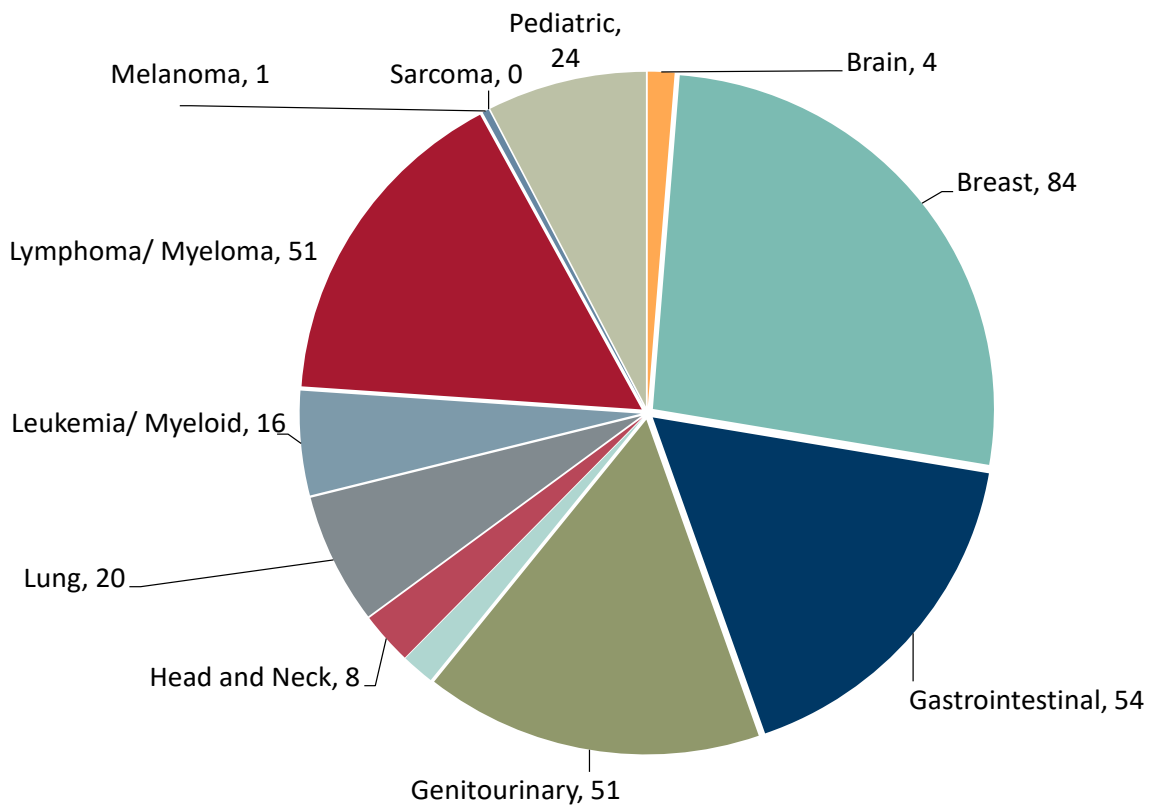
Early-phase KU CRC Patient Visits



Later-phase Clinical Trial Accruals



Later-phase Clinical Trial Accrual by Disease Group



Clinical Trials Patient Total By Location

Interventional treatments

Site Location	Patient Total
KU Clinical Research Center (early phase)	97
Westwood and KU Hospital (later phase)	214
KU Cancer Center Community sites	57
Masonic Cancer Alliance sites	12
Children's Mercy	24
Other sites	7

Top Five Counties for KU CRC Patient Visits

	County	Unique Patients
1	Johnson (KS)	792
2	Jackson (MO)	523
3	Leavenworth (KS)	153
4	Clay (MO)	133
5	Wyandotte (KS)	127

Services to Support Clinical Trials

Correlative Laboratories

The correlative laboratory is staffed and operated by the Clinical Pharmacology division of KU Cancer Center. This lab provides trained staff and equipment for the acquisition, processing, storage, and shipment of biological samples generated from clinical studies including blood, urine, ascites fluid and tissue samples. The Correlative Laboratories provide critical support for more than 200 cancer clinical trials and approximately 8 non-cancer trials.

Bioanalytical Laboratory

The Bioanalytical Laboratory at KU CRC is a state-of-the-art facility for the support of clinical and translational studies. The Bioanalytical Lab develops, optimizes, validates and applies various methods to the identification and quantitation of drugs, drug metabolites, and other small molecules from clinical samples to generate data for assessment of either pharmacokinetics or for examination of biomarkers of effect.

Pharmacokinetic/Pharmacodynamic Services (PK/PD)

The mission of the PK/PD unit is to advise investigators on the incorporation of PK/PD to add value to clinical studies and to guide the experimental design to maximize this value. This includes the optimization of dosing and sampling protocols. Data generated by the Bioanalytical Laboratory or by third parties are used for pharmacokinetic calculations.

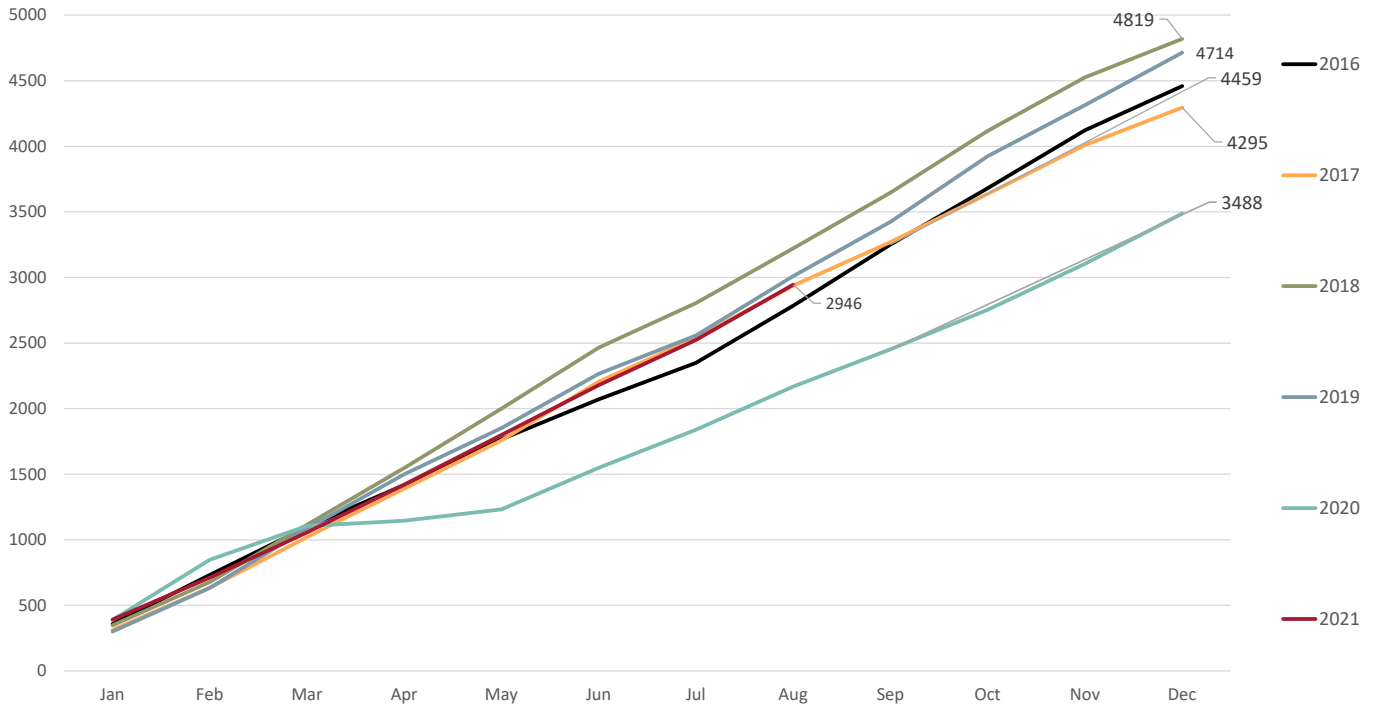


Other Organizations Conducting Research at the KU Clinical Research Center

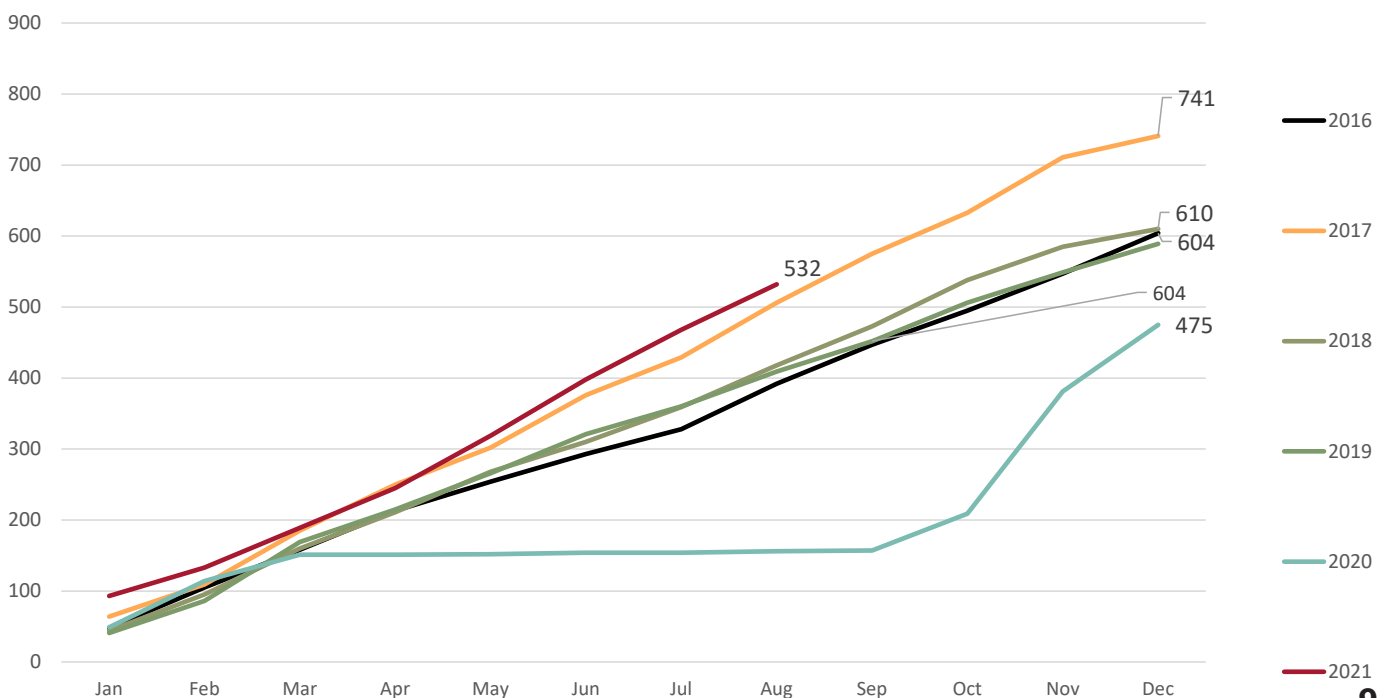
Clinical and Translational Science Unit (CTSU)

The CTSU provides the Kansas City region with a centralized resource for supporting clinical and translational research. The clinic and staff support both pharmaceutical trials and investigator-initiated trials for researchers mostly outside the oncology area, but some trials do support cancer and cancer survival.

Total CTSU Patient Visits



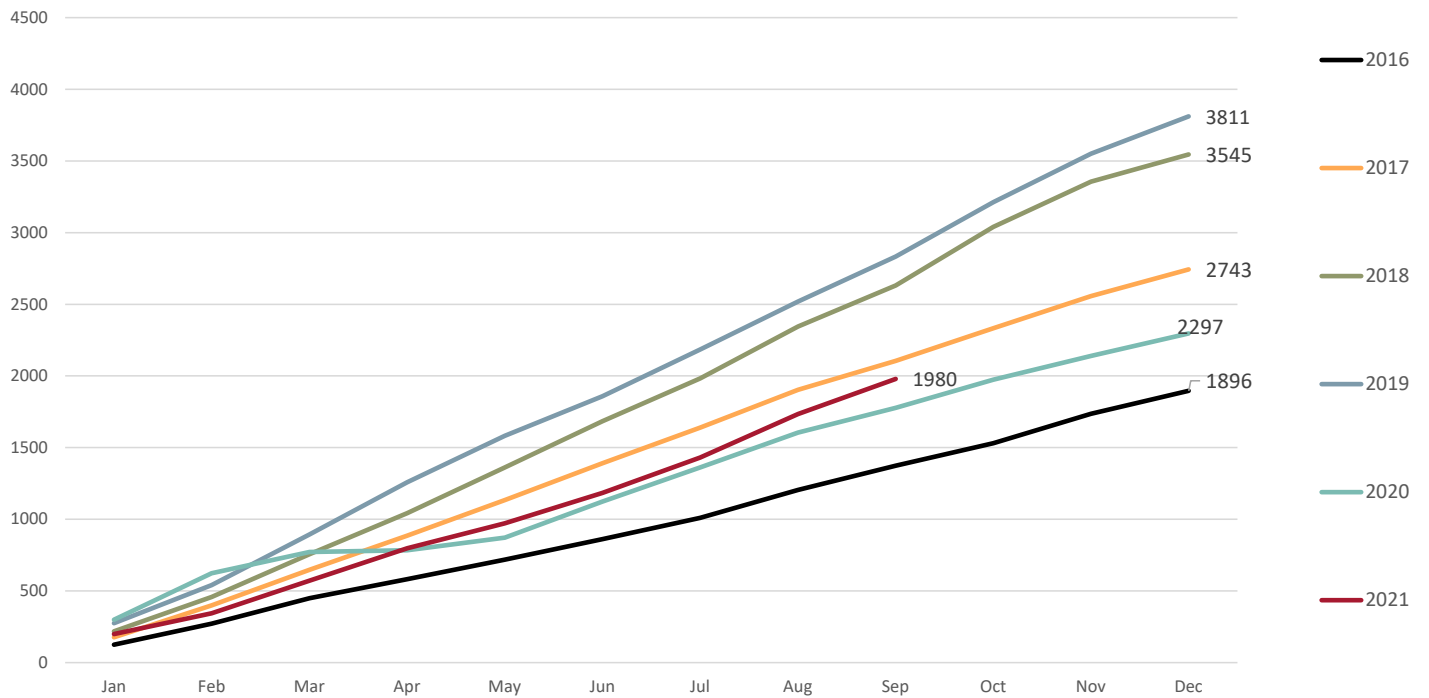
Total CTSU Patient Accrual



Alzheimer's Disease Research Center

The KU Alzheimer's Disease Research Center's mission is to improve the lives of patients and families with Alzheimer's disease by eliminating the disease through research into its treatment and prevention. It is one of only 33 NIH-funded Alzheimer Disease Centers. The clinical operations of the KU Alzheimer's Disease Research Center include both research and outpatient clinics which take place at the Clinical Research Center (CRC).

Alzheimer's Disease Research Center Patient Visits



Alzheimer's Disease Research Center

Since NIA funding began in 2011, the KU Alzheimer's Disease Research Center has supported 42 national and international pharmaceutical trials. We anticipate being a site for the newly FDA-approved medication for Alzheimer's disease treatment, Aduhelm (aducanumab), as part of a trial to prove clinical benefit post-approval.

International/Pharmaceutical Trials

Study	Sponsor	Enrollment to Date
A3-45*	NIH/Eli Lilly	7
ADNI3*	NIH/ATRI	19
Alector*	Alector	0
Bio-Hermes*	NIA	3
DAPA*	AstraZeneca LP	37
LIFE-DSR*	LuMind/ATRI	2
Trailblazer-2*	Eli Lilly	5
Trailblazer-Ext*	Eli Lilly	3
TRC PAD*	NIH	11
Vaccinex*	IQVIA	0
vCCC*	NIH	60
A4	NIH/Eli Lilly	20
AbbVie Open-label	AbbVie	6
LEARN	NIH/Eli Lilly	15
Embark	Biogen	4
PEGASUS	Amylyx	9
Clarity	Eisai	0
Generation 1	Novartis	13
Generation 2	Novartis	3
AbbVie	AbbVie	9
Trailblazer	Eli Lilly	5

*Currently enrolling studies

NIH=National Institutes of Health

Study	Sponsor	Enrollment to Date
ASPREE	NIH/Berman Center	41
Daybreak	Eli Lilly	3
EARLY	Janssen	1
ENGAGE	Biogen	8
TTP Open-label	vTv Therapeutics	4
TTP	vTv Therapeutics	14
LZAX	Eli Lilly	8
NEUROTROPE	Neurotrope	4
MK-8931	Merck	19
TCAD	NIH/Toyama	13
Elan 201	Janssen	3
IGIV	NIH/Baxter	11
Janssen 301	Janssen	2
Janssen 302	Janssen	5
Janssen 351	Janssen	6
Resveratrol	NIH	1
SNIFF	NIH/National Institute of Aging	2
SUMMIT AD	Janssen	11
Wyeth-3001	Wyeth	2
Exelon Patch	Novartis	8
Exelon Patch-open label	Novartis	6
TOTALS		403

Alzheimer's Disease Research Center

The KU Alzheimer's Disease Research Center has supported 53 investigator-initiated studies resulting in 2,911 enrollments to date.

Investigator-Initiated Trials

Study	Sponsor	Enrollment to date
ADRC Clinical Cohort*	NIH	427
ADMIT*	NIH	52
AEROBIC*	NIH	26
Alianza Latina Interviews	NIH	41
AMIE*	KU Endowment	2
AROMA*	NIH	47
BB8-AD*	NIH	40
Brain Healthy Diet*	NIH	23
Brain Healthy Soul Food Diet*	NIH	39
COMET*	NIH	0
CUIDATXT*	NIH	23
DYNAMIC*	NIH	78
GEM*	NIH	29
GETActive*	KUMC Pilot	20
IGNITE*	NIH	187
LEAN*	NIH	0
LEAP! Rx*	NIH	86
NICE*	NIH	151
SEAD2*	KUMC/Ausio	40
SIESTA*	NIH	42
STATINS*	NIH	25
TDAD*	NIH	15
ACCEL	KU ADRC Pilot	87
ADEPT	NIH	77
APEX	NIH	118
APP PET-Disclosure	NIH	315

Study	Sponsor	Enrollment to date
C-NAP	NIH	25
Diabetes and EF	Kansas Partners in Progress	8
ECEP	Internal Medicine	7
EXERT	NIH	10
FamTechCare	NIH	41
FRITO	KU Endowment	61
INFORM	NIH	52
KDRAFT	CTSA	15
Mediterranean Diet	Frontiers/KU ADRC Pilot	26
MILK	KU ADRC Pilot	3
MOVER	KU Endowment	45
MPA/ACCEL	KU ADRC Pilot	14
PACER	Ziegler Award	3
PACER 2	Foundation for Physical Therapy	24
POX	CTSA	6
Remote Monitoring	CTSA	6
REACT	NIH	68
REST	KU ADRC Pilot	3
RetinaAD	St. Luke's Hospital Foundation	36
rrAD	NIH	126
SBIR	NICHHD	33
SEAD	KUMC/Ausio	16
SPA	Alzheimer's Drug Discovery Association	20
TEAM	NIH	102
TOAD	Alzheimer's Association	32
TORTIAS	NIH	14
TrACR	KU ADRC Pilot/AHA	125
TOTALS		2,911

*Currently enrolling studies

CTSA=Clinical Translational Science Award

NIH=National Institutes of Health

NICHHD=National Institute of Child and Health Development

KPP=Kansas Partners in Progress

**Johnson County Education Research Triangle
KUMC Clinical Research Center Budget Report**

	Approved FY22 Budget			Actual FY22 as of 09/30/2021		
	JCERT	Other Sources	Total	JCERT	Other Sources	Total
Revenue						
JCERT Sales Tax	\$ 6,400,000		\$ 6,400,000	1,858,666		\$ 1,858,666
Clinical Trial Collection		7,000,000	7,000,000		1,047,204	1,047,204
Cancer Research Center Clinical Services		3,100,000	3,100,000		310,019	310,019
Cancer Center Support Grants for NCI-designated Cancer Centers		1,000,000	1,000,000		290,229	290,229
University of Kansas Hospital Community Support		1,182,100	1,182,100		237,483	237,483
KU Cancer Center Support		1,500,000	1,500,000		110,387	110,387
Facility Rent Collection		383,124	383,124		95,781	95,781
Common Area Maintenance Fee	-	336,822	336,822		84,205	84,205
Interest Earnings	15,000		15,000	623		623
Build America Bond Interest Subsidy	-	-	-	-	-	-
Total Revenue	6,415,000	14,502,046	20,917,046	1,859,289	2,175,308	4,034,597
Expenditures						
Payroll						
Director, Phase I Program & startup	78,622	189,386	268,008	13,611	31,230	44,841
Physician Positions	160,184	75,553	235,737	27,023	17,073	44,096
Research Leadership	171,451	258,328	429,779	-	103,314	103,314
Business Development	-	346,034	346,034	-	66,577	66,577
Research Scientists	149,505	74,256	223,761	6,351	-	6,351
Investigator Initiated Trial Staff	201,724	286,466	488,190	117,048	19,124	136,172
Research Laboratory Staff	347,725	419,071	766,796	91,511	87,056	178,567
Research Nursing, Study Coordination & Regulatory Administration	3,109,310	7,212,565	10,321,875	743,391	1,375,102	2,118,493
Budget & Finance Support	61,450	1,327,845	1,389,295	12,644	354,916	367,560
Total Payroll	4,619,556	10,934,113	15,553,669	1,069,205	2,239,197	3,308,402
Other Operating Expense						
Operating Expenses	126,200	650,000	776,200	14,571	192,370	206,941
Remodeling	75,000	-	75,000		-	-
Conference Room AV Upgrade	75,000		75,000			
Telephone & Networking	67,900	-	67,900	9,785	-	9,785
Mass Spec Lease	80,000		80,000	-	-	-
Clinical Trial Research Initiatives for Comprehensive Status	58,000	250,000	308,000	19,333	240	19,573
KUH Clinical Services Settlement Cost - Operations	-	3,100,000	3,100,000	-	555,737	555,737
KUH Clinical Services Settlement Cost - Facility Rent	-	383,124	383,124	-	95,781	95,781
KUH Clinical Services Settlement Cost - Common Area Maintenance		336,822	336,822		84,205	84,205
Total Other Operating Expense	482,100	4,719,946	5,202,046	43,689	928,333	972,022
Facility Expense						
Facility Operations	954,700	-	954,700	209,088	-	209,088
Withheld by Trustee for Debt Service & Trustee Expenses	905,156	-	905,156	200,000	-	200,000
Total Facility Expense	1,859,856	-	1,859,856	409,088	-	409,088
Total Expenditures	\$ 6,961,512	\$ 15,654,059	\$ 22,615,571	\$ 1,521,982	\$ 3,167,530	\$ 4,689,512
Revenue less Expenditures	(546,512)	(1,152,013)	(1,698,525)	337,307	(992,222)	(654,915)
Less Current Amount Set aside for Capital Reserve	400,000	-	400,000	100,000	-	100,000
Less Current Amount Set aside for Operations	200,000	(1,100,000)	(900,000)	50,000	-	50,000
Operating Account - Beginning Balance	2,096,720	150,733	2,247,453	2,843,630	231,930	3,075,560
Operating Account - Ending Balance	\$ 950,208	\$ 98,720	\$ 1,048,928	\$ 3,030,937	\$ (760,292)	\$ 2,270,645